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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 121934.00002	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US04/12061	International filing date *(day/month/year)* 20 April 2004 (20.04.2004)	Priority date *(day/month/year)*
International Patent Classification (IPC) or national classification and IPC IPC: **A61M 15/00**(2006.01),**16/00**(2006.01) USPC: 128/202.22,204.23,205.29,205.25,206.24;73/40		
Applicant CRUTCHFIELD, CLIFTON D		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 February 2006 (17.02.2006)	09 March 2007 (09.03.2007)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Justine Yu Telephone No. 571-727-3700

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/12061

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description:
pages 1-24 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages 25-28, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-2, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☒ the claims, Nos. 4

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-3,5-20	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-3,5-20	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-3,5-20	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-3, and 5-20 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest (1) an apparatus for fit-testing a respirator, comprising a switch operably connected to a means for closing a breathing port of said respirator, wherein activation of the switch closes said breathing port of said respirator and initiates a controlled negative pressure testing protocol when intra-respirator pressure substantially equal ambient pressure; and/or (2) a method for fit testing a respirator having a breathing port comprising the steps of activating a switch and closing a breathing port of said respirator, thereby initiating a controlled negative pressure testing protocol when intra-respirator pressure substantially equals ambient pressure. Thus, the invention defined in claims 1-3, and 5-20 is considered novel.

Claims 1-3, and 5-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

1. (Currently Amended) A method for fit testing a respirator having a breathing port, comprising the steps of:

a. placing the respirator on a test subject's face,

b. having the test subject hold his breath,

c. activating a switch and closing a breathing port of said respirator, thereby initiating a controlled negative pressure testing protocol when intra-respirator pressure substantially equals ambient pressure;

[[c]] d. producing and maintaining a predetermined level of vacuum in the respirator; and

[[d]] e. measuring a flow rate of air necessary to maintain said level of vacuum[[,]] ~~wherein said steps of producing a vacuum in the respirator and measuring said flow rate of air are initiated simultaneously by the activation of a switch~~ .

2. (Original) The method of claim 1, wherein the test subject inhales before holding his breath.

3. (Original) The method of claim 1, wherein the switch is activated by the test subject.

4. (Cancelled).

5. (Currently Amended) The method of claim [[4]] 1, wherein said step of producing and maintaining a predetermined level of vacuum in the respirator comprises monitoring internal respirator pressure to ensure that said pressure returns to an ambient pressure before the breathing port is closed.

6. (Original) The method of claim 1, wherein said step of producing and maintaining a predetermined level of vacuum in the respirator comprises closing the breathing port by generating an air pressure sufficient to move a diaphragm within the breathing port into an air-sealing position.

7. (Original) The method of claim 1, wherein said steps of producing and maintaining a predetermined level of vacuum in the respirator and measuring a flow rate of air necessary to maintain said level of vacuum comprise exhausting air from the respirator

to generate and maintain a desired negative challenge pressure inside the respirator for a specified test period, whereby the challenge pressure is held constant, and measurement of a piston displacement rate yields a direct measure of an air leakage rate into the respirator.

8. (Original) The method of claim 1, wherein release of the switch results in the opening of the breathing port.

9. (Original) The method of claim 7, wherein internal respirator pressure is progressively reduced to the negative challenge pressure in order to limit challenge pressure overshoot.

10. (Original) The method of claim 9, wherein internal respirator pressure is progressively reduced to the negative challenge pressure by adjusting a motor control logic of a vacuum source based on the following iterative algorithm:

if in-mask pressure $\leq$ 25% of challenge pressure, set AFR = 3 x AFR and PLR = 3 x PLR; else

if in-mask pressure $\leq$ 50% of challenge pressure, set AFR = 2 x AFR and PLR = 2 x PLR; else

if in-mask pressure $\leq$ 75% of challenge pressure, set AFR = 1.5 x AFR and PLR = 1.5 x PLR; else

if in-mask pressure > 75% of challenge pressure, enter track phase of test,

wherein AFR is attack flow rate and PLR is presumed mask leak rate.

11. (Original) The method of claim 7, wherein said internal respirator pressure is progressively stepped down to the negative challenge pressure by adjusting motor control logic of a vacuum source based on the following iterative algorithm:

if challenge pressure overshoot > 3 x challenge pressure, set AFR = AFR/3 and PLR = PLR/3; else

if challenge pressure overshoot > 2 x challenge pressure, set AFR = AFR/2 and PLR = PLR/2; else

if challenge pressure overshoot > 1.5 x challenge pressure, set AFR = AFR/1.5 and PLR = PLR/1.5; else

if challenge pressure overshoot > 1.25 x challenge pressure, set AFR = AFR/1.25 and PLR = PLR/1.25; else

proceed with fit test using current aggressive initial piston pull,

wherein AFR is attack flow rate and PLR is presumed mask leak rate.

12. (Original) The method of claim 7, wherein said measurement of a piston displacement rate further comprises:

a. storing pressure and leak flow rate information in an array during a track phase of the fit test; and

b. applying a post-test analysis algorithm to integrate all acceptable leak measurements while excluding those segments of the track phase that do not meet predetermined pressure criteria,

wherein an acceptable pressure bin is defined as a minimum portion of the track phase during which contiguous in-respirator pressure measurements all fall within a specified range of said challenge pressure.

13. (Original) The method of claim 7, wherein said measurement of a piston displacement rate further comprises:

a. identifying periods or bins of acceptable pressure tracking,

b. determining whether an acceptable number of such bins was produced during the fit test; and

c. integrating the flow rate measurements associated with each bin to determine the mean respirator leak rate for that specific test.

14. (Original) The method of claim 13, wherein test quality is quantified as a function of the number of acceptable pressure bins recorded during the fit test.

15. (Original) The method of claim 14, wherein said function comprises:

if bins > 3, then report measured leak rate; else

if 3 > bins > 0, then report estimated leak rate; else

if bins = 0, then report retry test.

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16. (Original) The method of claim 12, wherein said specified range of said challenge pressure comprises ± 10%.

17. (Currently Amended) An apparatus for fit-testing a respirator, comprising:

a leak rate analyzer in closed gaseous communication with said respirator, wherein said leak rate analyzer comprises an air-pressure transducer operably connected to said respirator, a vacuum source responsive to said air-pressure transducer to maintain a predetermined vacuum level in the respirator, ~~; and~~ an air-flow measuring device in gaseous communication with said respirator and said vacuum source; and a switch operably connected to a means for closing a breathing port of said respirator, ~~and wherein said vacuum source and said air-flow measuring device are simultaneously activated by a switch~~, wherein activation of the switch closes said breathing port of said respirator and initiates a controlled negative pressure testing protocol when intra-respirator pressure substantially equals ambient pressure.

18. (Original) The apparatus of claim 17, wherein said air-flow measuring device and said vacuum source comprise a piston.

19. (Original) The apparatus of claim 18, wherein said piston is controlled by a stepper motor.

20. (Original) The apparatus of claim 18, wherein a by-pass orifice is present in tubing disposed between said piston and said leak rate analyzer.